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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/731,699
Filing Date: December 09, 2003
Appellant(s): JANZIG ET AL.

Daniel T. Lund
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/22/08 appealing from the Office action mailed 10/25/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,934,368	Lynch	6-1990
5,312,440	Hirschberg et al	5-1994
5,645,586	Meltzer	7-1997
7,212,864	Wahlstrand et al	5-2007

(9) Grounds of Rejection

Claim 25 stands rejected under 35 U.S.C. §102(b) as being anticipated by Lynch (US 4,934,368). Lynch is considered to disclose:

a first module comprising implant case 12, and

a second module comprising nerve cuff 2, and

a coupling module comprising lead 3.

The coupling module (lead 3) is inherently hermetically sealed to both housing using silicone rubber.

Claims 7-11, 14, 15, 17 and 20-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hirschberg et al (US 5,312,440). Hirschberg et al is considered to disclose:

a first module comprising housing 15, and

a second module comprising implantable defibrillator 1, and

a coupling module comprising lead 9.

Lead 9, terminals 7 and 16 are inherently hermicically fixed to the first and second housing to prevent bodily fluids from entering and shorting the electrical connections.

Claims 1, 3-6 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lynch (US 4,934,368).

Lynch discloses all of the claimed features except for an overmold that at least partially encapsulates each of the housings and a thickness of between approximately 4 millimeters and approximately 8 millimeters.

Lynch teaches the point where the lead 3 enters the case 12, a layer of silicone rubber 25 is applied to absorb lateral strain on the lead. Further, the cuff 2 may either be formed integrally with the lead 3 or formed separately and sealed to the lead 3 by a dip coat of silicone rubber.

One of ordinary skill in the art would have found it obvious to coat both the case 12 and the lead 3 with a dip coating of silicone because Lynch teaches the layer of soft silicone 25 is applied after the lead and case have been assembled and because a dip coating is also an after an assembly process.

Claims 12, 13, 18 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hirschberg et al (US 5,312,440).

Hirschberg et al disclose all of the claimed features except for a hermetically fixed attachment, a weld joint, or a bellows section.

One of ordinary skill in the art would have found it obvious to weld the titanium to make a hermitic seal to prevent corrosion and seal out bodily fluids. A bellows would be an obvious addition to permit axial flexibility to permit easier use of the housing 15. Hirschberg et al provide motivation by teaching the structure of the housing can be altered dependent on the implantation location in the body of the patient.

Regarding claim 19, one of ordinary skill in the art would have found it obvious to include a third module because Hirschberg et al teach the illustrated selection and arrangement of the components in housing 15 are considered only as examples and that a plurality of further possible combinations are within the scope of disclosed invention. A third module would be within the scope of expected possible combinations.

Claims 7, 8, 19 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Meltzer (US 5,645,586).

Meltzer shows all of the claimed features except for a coupling module that defines at least one lumen between the first and second housings. One of ordinary skill in the art would have found it obvious to modify the device of Meltzer to include a

coupling module that defines at least one lumen between the first and second housings because Meltzer teaches the number of housing segments, as well as the manner in which the housing segments are joined for pivotal movement, may take many forms, depending upon the application.

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Pat. No. 7,212,864. The two modules of the claimed application possess an identical housing to that of the copending application. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to provide an implantable medical device for implantation in the head of a patient with variations of a first and second module including a flexible overmold to cover the modules.

(10) Response to Argument

Lynch does not appear to teach away from the concept that implant case 12 and nerve cuff 2 are each hermetically sealed to lead 3. To the contrary, if they were not hermetically sealed to lead 3, they would be inclined to permit bodily fluids to seep into lead 3 which would greatly increase the likelihood the device would malfunction, or toxify the patient. Not explicitly discussing a particular feature, does not suggest a teaching away; otherwise, there would never be inherency. Not expecting that hermetical sealing of implant case 12 or nerve cuff 2 of Lynch to be necessary is contrary to what would be reasonably expected for any implant, i.e. a hermetic seal. "Positive environmental protection" is a hermetic seal because both are synonymous with making an enclosed region impervious to outside interference or influence. Assuming that positive environmental protection refers to a level of sealing different than a hermetic seal does not follow from the context and such an assumption is unsupported by any disclosure presented in Lynch. Because master circuitry case 8 is

disclosed as being hermetically sealed, and because master circuitry case 8 is contained entirely within implant case 12, which provides positive environmental protection, one of skill in the art would assume that positive environmental protection is a level of sealing that is equal to hermetic sealing.

It is unreasonable to conclude hermetically sealing both implant case 12 and master circuitry case 8 would add unnecessary expense to the manufacture of a neurological stimulation apparatus disclosed by Lynch. Lynch teaches double wall sealing is justified, "*double wall/double environmental protection is a highly desirable feature of this invention for providing long term reliability of the implant case 12, since the consequences of a failure in the case 12 are additional surgery and the attendant suffering by the patient.*" See col. 7, lines 54-63.

If implant case 12 were hermetically sealed, then

There at least two reasons for implant case 12 to be hermetically sealed, even though master circuitry case 8 is contained entirely within implant case 12.

Reason 1, double wall protection is highly desirable, as stated above.

Reason 2, since circuitry case 8 is hermetically sealed, a double environmental protection would necessitate implant case 12 also be hermetically sealed.

Fig. 9 of Lynch clearly shows a unified-construction between lead 3 and nerve cuff 2, thus obviating the need to teach or suggest any level of sealing between lead 3 and nerve cuff 2.

Applicant's assertion is without merit that with respect to the connection between lead 3 and nerve cuff 2, Lynch fails to teach or suggest any level of sealing.

Lynch discloses the cuff 2 may either be formed integrally with the lead 3 or formed separately and sealed to the lead 3, for example, by a final dip coat of silicone rubber with the electrodes masked. See col. 8, lines 29-35.

The Office Action does not assert that Lynch actually demonstrates that silicone rubber does not provide a hermetic seal.

Lynch discloses implant case 12 includes outer seal 13 and inner seal 14 to provide a double environmental seal. The interior shaft of each seal 13 and 14 is formed with circular sawtooth ridges for gripping lead 3. Lead 3 is made of

compressible silicone material and is drawn through seals 13 and 14 during assembly. A layer of silicone 25 is applied after the case 12 and leads 3 have been assembled.

Outer seal 13 and inner seal 14 in addition to providing a double seal, provide a double fixation of lead 3 through the sawtooth ridges.

Silicone rubber 25 in addition to providing a complete seal (the silicone requires cutting, if lead 3 needs to be replaced), absorbs any lateral strain on the lead 3.

With respect to claim 7, Hirschberg teaches and suggests a coupling module that is made of a metal that defines at least one lumen, lead 9. It is unreasonable to interpret lead 9 as any type of lead other than a wire with insulation. If it were any type other than a wire conductor surrounded with insulation, Hirschberg et al would have described how it was different from a conventional electrode lead in order to have an adequate disclosure. Applicant's arguments acquiesce lead 9 may for arguments sake, comprise a metal, but not a metal that defines a lumen. If lead 9 were a bare metal conductor without surrounding insulation, the device would not function as intended because the lead would conduct to adjacent tissue and not the heart. Also, structurally a lead is differentiated from an electrode by having an insulation covering.

Applicant argues hermetic fixation would not be necessary or obvious to prevent shorting in the Hirschberg device. This is contrary to accepted implantable device requirements. An implantable device must not be prone to bodily fluid seepage which may not only render the device inoperable, but may cause bodily harm through toxicity. Hirschberg discloses a housing *adapted* for in vivo implantation in a patient. It is reasonable to view this *adaptation* as the housing being hermetically sealed, where a hermetic seal means "completely sealed." See American Heritage Dictionary.

Regarding Applicant's argument's directed toward claims 9 and 10, lead 9 has two ends with a lumen at each end sharing the same axis making the lumens co-axial lumens

Regarding Applicant's argument's directed toward claim 14, any structure that exists has a variation in cross-sectional shape.

Regarding Applicant's argument's directed toward claim 15, Hirschberg et al show lead 9 in Fig. 1, for example, with a curve portion. Helical refers to having the

form of a helix or spiral. A helical portion clearly corresponds to a portion of a helix which may comprise at least a curve portion.

Regarding Applicant's argument's directed toward claim 17, Hirschberg et al teach the housings 2 and 15 have the metal titanium. The coupling module comprises lead 9 and is made of the titanium metal that defines at least one lumen between the first housing 15 and second housing 2. Claim 17 requires the coupling module be made of titanium that defines at least one lumen between the first and second housings. The lumen through which lead 9 passes comprises the coupling module made of titanium.

Applicant's argument's directed toward claim 13, that a bellows section would serve no apparent purpose in the implantable defibrillator disclosed by Hirschberg et al is without merit. Just as lynch teaches silicone rubber 25 absorbs any lateral strain on the lead 3, a bellows section would be an obvious addition to permit axial flexibility to permit easier use of the housing 15.

Applicant's remarks directed to GROUP 11-(Claims 1, 3, 5 and 24) that a dip coating of silicon (silicone) on each of cuff 2, lead 3 and case 12 would likely be more difficult to remove than a layer of silicon (silicone) 25 only where lead 3 enters case 12, which could make it more difficult to replace a lead is contrary to a reasonable interpretation of the coating process. The dip coating would probably be easier to apply, since only one step is required to apply a coating to the whole device. Also, a dip coating would cover any imperfections resulting from lead replacement that would otherwise compromise the integrity of the silicone seal. It is unclear how or why Applicant considers the strain absorbing characteristics to be any different for a dip coating. If there is a difference, however small, it would appear the dip coating would provide a more uniform coating so strains in the coating would necessarily be more evenly distributed.

Regarding Applicant's argument's directed toward claim 4, lead 3 has two lumens.

Regarding Applicant's argument's directed toward claim 6, one of ordinary skill in the art would have found it obvious to measure a maximum thickness of between

approximately 4 millimeters and approximately 8 millimeters at an appropriate location of the device disclosed in Lynch.

Regarding Applicant's argument's directed toward Meltzer, one of ordinary skill in the art would have found a coupling module made of a metal that defines at least one lumen between the first and second housings as recited by claims 7 and 25 to be encompassing enough to be met by the teaching that the manner in which the housing segments are joined for pivotable movement may take many forms even when considered in the context of a hinged embodiment.

Applicant's remarks directed to GROUP 16-(Claim 1) that a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings differentiates claim 1 of the present application from claim 1 of US Pat. No. 7,212,864 and is not an obvious limitation is without merit. Claim 1 of US Pat. No. 7,212,864 recites a flexible overmold that covers a second module and partially covers the first module. Clearly, it would be an obvious modification to form a coupling module based on the characteristics of the flexible overmold to define a coupling module that is coupled to each of the modules, and defines at least one lumen, for example, an open gap of separation between the two housings.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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